

12

**EUROPEAN PATENT APPLICATION**

21 Application number: 88121221.1

51 Int. Cl.<sup>4</sup>: **A61M 5/00**

22 Date of filing: 19.12.88

30 Priority: 21.12.87 US 135581  
09.03.88 US 166046  
07.09.88 US 241352

43 Date of publication of application:  
28.06.89 Bulletin 89/26

84 Designated Contracting States:  
**AT BE CH DE ES FR GB GR IT LI LU NL SE**

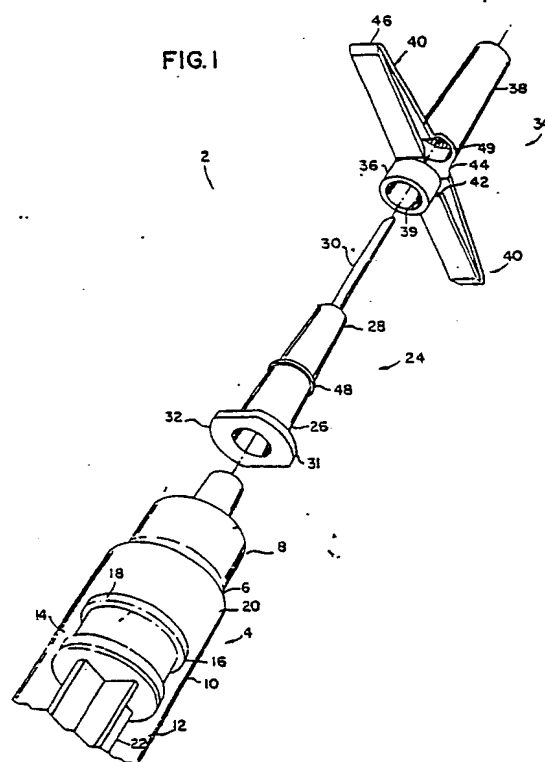
71 Applicant: **Dolgin, Stuart M.**  
**95 Belvedere Drive**  
**Syosset, NY 11791(US)**

72 Inventor: **Dolgin, Stuart M.**  
**95 Belvedere Drive**  
**Syosset, NY 11791(US)**  
Inventor: **Torbet, Philip**  
**26 Centre View Drive**  
**Upper Brookville, NY 11771(US)**

74 Representative: **Perani, Aurelio et al**  
**c/o JACOBACCI-CASETTA & PERANI 7, Via**  
**Visconti di Modrone**  
**I-20122 Milano(IT)**

54 Fluid passing apparatus with means for covering the same.

57 Apparatus for passing a fluid into or out of a warm-blooded animal which includes a fluid containing body, a needle assembly releasably mountable on the exterior surface of the body, a plunger for urging fluid into or out of the body and an externally mounted cap or retraction device for automatically covering the needle after it has been used and preventing the needle from reentering the aperture in the body.



**EP 0 321 903 A2**

## FLUID PASSING APPARATUS WITH MEANS FOR COVERING THE SAME

The present invention is directed to an apparatus for passing a fluid through an aperture including means for conveniently and effectively covering the apparatus after use and particularly to syringes in which the needle is automatically covered after use by a cap or is retracted into the barrel of the syringe and is thereafter prevented from reentering the aperture.

Over the past several years, the medical profession has been extremely concerned about exposure of medical personnel to patients and fluid samples infected with communicable diseases, and particularly AIDS. In an effort to minimize the risk of infection, medical personnel have donned masks, gloves and other protective devices in the treatment of patients.

One of the ways in which medical personnel can be subjected to a communicable disease is through the handling of devices which are designed to inject or withdraw a fluid from a patient (e.g., a hypodermic syringe, and the like). Once the syringe is contacted with the patients blood through the injection process, it becomes a high-risk potential carrier of infectious disease.

Accordingly, the medical profession has recognized the need for a convenient and efficient means of protecting medical personnel from contaminated needles. One of the first major advancements in this area was the development of the disposable syringe.

The most common disposable syringe contains a fluid-containing barrel and a movable plunger therein. The top end of the barrel has a collar having an open ended cavity with grooves for removably securing therein a needle assembly. The needle assembly includes a rigidly fixed needle mounted in a base which is screwed into the cavity of the collar. The needle is covered with an elongated snap-on cap which is removed prior to use. In order to operate the syringe, a suitable needle assembly with the cap in place is twisted onto the collar of the syringe. The cap is removed and the needle is ready to be injected into the patient. After use, the cap is held in one hand and the needle assembly in the other hand. The user must then carefully place the cap over the needle and push downward until the cap snaps in place. The entire syringe may then be discarded. Such syringe devices enable a barrel to be used interchangeably with any size needle since the barrels and needle assemblies are typically packaged separately.

Despite the reduction in handling time, such disposable syringes have not allayed the concerns of the medical profession regarding the risk of

infection by an exposed contaminated needle. This is because the elongated cap must be slowly and very carefully secured over the exposed needle thereby requiring complete concentration by the user.

In the often hectic and sometimes frantic performance of medical services, the user of such hypodermic needles often misaligns the cap and needle leading to needle pricks of the hand or arms. Such accidents occur because it is difficult to cover the needle properly under typical medical facility conditions. Accordingly, there have been efforts to provide a convenient and efficient means of covering contaminated needles to prevent post-use needle pricks.

Such efforts have focused on two methods of covering the needle. The first is to employ a cover which can be moved upwardly and over the needle and the second is to retract the needle within the barrel of the syringe. The use of a cover is exemplified by Sampson et al., U.S. Patent No. 4,425,120; Mitchell, U.S. Patent No. 4,631,057; Strauss, U.S. Patent No. 4,664,645; and Fox, U.S. Patent No. 4,695,274.

Syringe devices of the second type employing means for retracting the needle into the body of the syringe are shown in Vining et al., U.S. Patent No. 4,507,117; Jagger et al., U.S. Patent No. 4,592,744; DeLuccia, U.S. Patent No. 4,675,005 and Haber et al U.S. Patent No. 4,710,170.

The aforementioned devices have not gained commercial acceptance because they are complicated, difficult to manufacture and/or require substantial redesigning of the previously described standard syringe. More specifically, some such devices have a prepacked needle of a particular size which is loaded from within the barrel. As a result, the needle assemblies are not interchangeable with the standard barrel which adds to the cost of the syringe and makes the syringe less efficient to use. Furthermore, some of the prior devices do not permit external loading of the needle assembly on the top exterior surface of the barrel which also adds to the cost of the syringe.

Commercial efforts at capping contaminated needles have essentially rejected the complex and costly devices disclosed by the aforementioned patents. Instead, hospitals, clinics and individual medical practitioners have opted for systems which remove and store contaminated needles using devices which are separate and apart from the syringe itself.

One such device is sold under the trademark VACUSAFE and includes a container for storing contaminated needles. The top of the container has

a V-shaped hole with a serrated or gripping side that grips the needle assembly placed therein and dislodges it from the syringe when the syringe is rotated by the user.

Another such device is sold under the trademark DESTRUCTOCLIP which is similar to VACUSAFE but has the added feature of cutting off the tip of the needle while the syringe is held in the hole in the top of the container.

While these systems are effective once the syringe is inserted through the opening of the device, they are disadvantageous because the contaminated needle must be moved in its exposed condition from the patient to the place where the storage container is located. Thus, the contaminated needle is exposed for an unacceptable period of time during which the risk of accidental contact with the user, the patient or other personnel is high.

It is therefore an object of the invention to provide a convenient and effective manner of promptly covering contaminated parts of a fluid passing device.

It is a further object of the invention to provide a disposable syringe in which a contaminated needle is promptly removed from any possible detrimental contact with the user, the patient or other personnel.

It is a still further object of the invention to provide a means of covering the needle of a disposable syringe of the type in which the needles and barrels are interchangeable.

It is another object of the invention to provide a disposable syringe in which the needle assembly is covered by a cap activated from a location which is remote from the contaminated needle tip.

It is another object of the invention to provide a disposable syringe in which the contaminated needle assembly is retracted into the barrel of the syringe from a location which is remote from the contaminated needle tip.

It is a still further object of the invention to provide a disposable syringe in which the used needle is prevented from reentering the aperture of the needle assembly.

The present invention is generally directed to an apparatus for passing a fluid through an aperture in which it is desirable to cover the apparatus and protect the user from contamination after the apparatus has been used. In one form of the invention, the fluid passing apparatus is designed to inject or withdraw a fluid from a warm-blooded animal or the tissue of a warm-blooded animal.

The apparatus comprises a body adapted to contain the fluid such as a barrel of a syringe or the body may itself contain a removable vial for the receiving of a fluid (e.g., blood) from a warm-blooded animal.

The size of the body or the vial contained within the body is unlimited and therefore the invention is not limited by the amount of fluid which is passed through the apparatus. Typical examples of such devices include the standard barrel type syringe, blood drawing apparatus and the like.

The apparatus of the invention also includes a fluid passing means such as a needle assembly in flow communication with the barrel which is adapted to penetrate the animal tissue. The needle assembly is affixed to the top exterior surface of the barrel either by rotation into a groove or press-fitting so that different sized needles may be used interchangeably with a standard barrel. The invention also includes means for covering the fluid passing means either by a cover which is activated at a location remote from the fluid passing means or by retracting the fluid passing means within the barrel of the device. Means are also provided for automatically preventing the needle from reentering the aperture upon activation of the cover or by retraction of the needle into the barrel.

The following drawings in which like reference characters indicate like parts are illustrative of embodiments of the invention and are not meant to limit the scope of the invention as encompassed by the claims forming part of the application.

FIGURE 1 is a partial exploded view of one embodiment of a syringe in accordance with the present invention employing a double-winged cap for covering the needle;

FIGURE 2 is a partial cross-sectional view of the embodiment shown in FIGURE 1;

FIGURE 3 is a cross-section view of another embodiment of the invention employing a single-winged cap with the wing folded upwards to facilitate packaging;

FIGURE 4 is a partial exploded view of another embodiment of a syringe in accordance with the present invention employing a cap for covering the syringe;

FIGURE 5 is a partial cross-section view of the embodiment shown in FIGURE 4;

FIGURE 6 is a side view of the embodiment shown in FIGURE 4 showing the means for retaining the needle in the exposed position;

FIGURE 7 is a partial exploded view of another embodiment of a syringe in which the needle assembly is retracted within the barrel;

FIGURE 8 is a partial cross-sectional view of the embodiment shown in FIGURE 7;

FIGURE 9 is a partial cross-sectional view of another embodiment of a syringe in which the needle assembly is retracted within the barrel;

FIGURE 10 is a cross-sectional view of still another embodiment of a syringe in which the needle assembly is retracted within the barrel;

FIGURE 11 is partial exploded view of a further embodiment of a retractable syringe in which the needle assembly is retracted within the barrel;

FIGURE 12 is a cross-sectional view of the embodiment shown in FIGURE 11;

FIGURE 13 is a cross-sectional view of an embodiment similar to the embodiment shown in FIGURES 11 and 12 with means for cocking the needle upon retraction into the barrel to prevent reentry; and

FIGURE 14 is a cross-sectional view of another embodiment of the invention similar to FIGURE 9 with an inner wall of the plunger adapted to push against the detent extending from the needle assembly whereby the needle assembly is cocked in the barrel as it is retracted.

Referring to the drawings and particularly to FIGURES 1, 4, 7 and 11, the fluid passing device 2 generally includes a barrel section 4 having a top end 6 having mounted thereon a collar 8. The barrel section 4 is typically cylindrical, but may be four-sided having a substantially square-configuration as described hereinafter, and has a wall 10 defining a cavity 12 for receiving or ejecting a fluid such as blood or a drug solution. The barrel section 4 may also contain a standard vial (not shown) for storing blood received from the patient.

Within the cavity 12 is a plunger 14 including a head section 16 having a wall 18 which communicates with the interior of the wall 10 of the barrel 4 to provide a sealed chamber 20 which contains the fluid. The volume of the sealed chamber 20 increases when the plunger 14 is pulled back and decreases when the plunger 14 is pushed forward due to the seal formed by the contact of the wall 18 of the head section 16 with the interior surface of the wall 10. The plunger 14 has a stem 22 connected to the head section 16 at one end and to a handle (not shown) at the other end as is well known in the art.

The fluid passing device 2 also includes a needle assembly 24 which includes a base 26 and a neck region 28. A needle 30 or other fluid passing means is rigidly fixed within the neck region 28. As shown in the drawings, the needle 30 is relatively short for the sake of convenience. It should be understood that the present invention is adapted to facilitate the use of any size length and diameter needle.

The needle assembly 24 also includes a securing means 32 for attaching the needle assembly 24 to the collar 8 of the fluid passing device 2. As shown in FIGURES 1 and 2, the securing means 32 may include an arcuate side surface 31 which serves as a thread that may be reversibly locked within a groove 33 (see FIGURE 2) within the collar

8 by rotating the needle assembly 24.

The present invention also includes means 34 for covering the needle 30 after it has been used, the cover means 34 being movable from a retracted position in which the needle 30 is exposed ready for use to an extended position where the cover means 34 extends above and over the needle 30.

Referring to FIGURES 1 and 2, the cover means 34 comprises a bottom portion 36 and a top portion 38, an axial hole 39 therethrough and an aperture 41 through which the needle 30 protrudes when the cover means 34 is in the retracted position. A pair of folded arm sections 40 are connected to the bottom 36 and top 38 portions through hinges 42 and 44, respectively. The arms 40 are extendable about a flexible hinge section 46 and hinges 42 and 44. The cover means 34 including the arms 40, hinges 42, 44 and 46 are preferably made of a flexible plastic such as polypropylene or polyethylene.

Between the base 26 and the neck region 28 of the needle assembly 24 is a flange 48. In factory assembly, the cover means 34 is inserted over and secured to the needle assembly 24 by placing the needle 30 within the axial hole 39 and moving the cover means 34 downward and over the flange 48 until the interior surface 43 of the bottom portion 36 is taper locked or otherwise securely locked onto the base 26. The top portion 38 is retracted until the annular groove 49 is releasably locked over the flange 48.

The fluid passing device 2 shown in FIGURE 1 may be sold as individual components or as a self-contained unit. When sold as individual components, the needle 30 of the needle assembly 24 is capped with a standard snap-on type elongated cap. In the form of a self-contained unit, the cover means 34 is secured to the needle assembly 24 by the interlocking of the flange 48 within the groove 49. The standard elongated cap is secured over at least the portion of the needle 30 which protrudes beyond the top of the axial hole 39 when the arms 40 of the cover 34 are in the retracted position shown in FIGURES 1 and 2. The present invention, however, is not limited to any particular manner of packaging the components of the invention.

As best seen in FIGURE 2, the needle 30 is exposed and ready for use when the elongated cap (not shown) is removed and the arms 40 are in the radially extended position corresponding to the cover 34 being in the retracted position as previously described. After use, the contaminated needle 30 is covered by pushing the arms 40 inwardly at the hinge section 46. This causes the flange 48 to disengage from the annular groove 49 and the top portion 38 of the cover 34 to move upwardly along the axis of the needle 30 until the top end 52 of the

cover 34 extends above and over the needle 30.

The cover 34 of the present invention is also provided with means for insuring that the needle 30 can not reenter the aperture 41 once the cover 34 is extended above and over the needle 30. This is accomplished, for example, by making one of the arms 40 (e.g. the right arm) slightly longer than the other arm. This causes the cover 34 to move radially in the direction of the shorter arm once the top end 52 of the cover 34 has been raised above the needle 30. In this way, the tip of the needle 30 will come to rest on the right hand interior surface 50 (see FIGURE 2) of the top end 52 of the cover 34 corresponding to the longer arm 40. Of course, the needle 30 will come to rest on the opposite bottom surface of the top end 52 if the left arm 40 is made slightly longer than the right arm 40.

Re-emergence of the needle 30 through the aperture 41 may also be prevented by forming the aperture 41 with a downwardly extending conical tapered side 53. When the cover 34 is raised above the end of the needle 30 and the needle 30 comes to rest on the bottom interior surface 50, the needle 30 is prevented from moving radially toward the aperture 41 by the downwardly extending tapered side 53.

Referring to FIGURE 3, the cover 34 may be provided with a single arm 40 which operates in the same manner as the double arm embodiment shown in FIGURES 1 and 2. As the cover 34 is raised above and over the needle 30, the cover will cock away from this side of arm 40 causing the needle to rest on the interior surface 50 of the same side as the arm 40. The tapered side 53 may be employed to prevent reemergence of the needle 30 as described previously.

Furthermore, it may be desirable to package the cover 34 with the arms 40 extending axially and substantially parallel to the top portion 38 of the cover 34 as shown in the one arm embodiment of FIGURE 3. By positioning the arms 40 in this manner, the radial dimension of the cover 34 is significantly reduced thereby minimizing the size of the packaging. As is apparent from a comparison of FIGURES 2 and 3, the arms 40 may be easily moved from the axially extending position shown in FIGURE 3 to the radially extending position shown in FIGURE 2 by exerting downward pressure on the arms 40 in the general of hinge 46.

Referring to FIGURES 4 through 6, another embodiment is shown where the cover 34 comprises a cylindrical elastic body 60 having a flanged base 62 and a rigid top end 64 having an aperture 66 for receiving the needle 30. The top end 64 also has a radially extending projection 67.

The needle assembly 24 includes the base 26 and neck 28. The needle assembly 24 also includes a securing means 32 including an arcuate

side surface 31 which serves as a thread that may be reversibly locked within a groove 33 as described in connection with FIGURES 1 through 3. The neck includes an outer wall 70, an inner needle mounting support 72 (See FIGURE 5) which surrounds and supports the needle 30. The outer wall 70 has a slot 71 for receiving the projection 67.

Between the outer wall 70 and the needle support 72 is an annular cavity 74 having a top open end 76 and a closed bottom end 78. The cover 34 is adapted to be inserted and secured within the cavity 74. The flanged base 62 is secured, preferably with the use of an adhesive, to the closed bottom end 78 of the cavity 74.

Due to the elasticity of the body 60, the body 60 can be compressed into the retracted position as shown in FIGURES 5 and 6 thereby exposing the needle 30. The needle assembly 24 and the cover 34 may be shipped assembled, compressed, and covered with an elongated needle cap (not shown). In this position, the projection 67 is secured within the slot 71. After use of the needle 30, the contaminated needle 30 is covered by disengaging the projection 67 from the slot 71 which causes the elastic body 60 to move to the extended position above and over the contaminated needle 30.

Means are provided for preventing the contaminated needle 30 from reentering the aperture 66 after the cover 34 has been released to the extended position as shown in FIGURE 4.

This can be accomplished, for example, by providing the flanged base 62 with an asymmetric width. More specifically, one portion 63a of the flanged base 62 has a width greater than the remaining portion 63b of the flanged base 62 as shown best in FIGURE 4. As a result, one side of the elastic body 60 (the right side as shown in FIGURE 4) is more tightly compressed than the opposed side of the elastic body 60. When the projection 67 is released from the slot 71, the cover 34 will rise above the needle 30 and move radially to the left because of the difference in compression between the right side of the body 60 and the left side. This is due to the shorter distance between the top surface of the flange portion 63a and the top of the cover 34, than the corresponding distance between the flange portion 63b and the top of the cover 34. As a result, the cover 34 will cock over to the left of the needle 30 once the cover 34 rises above the needle 30. The aperture 66 may also be provided with a conical tapered side 69 which prevents the needle 30 from reentering the aperture 66 as described previously in connection with FIGURE 2.

The embodiment of FIGURES 4 through 6 can be manufactured as individual components or as a

self-contained unit as described previously. In each case, a protective elongated snap-on cap is provided to cover the needle 30 before it is used.

Referring to FIGURES 7 through 12, embodiments of an externally loaded forward mounting needle assembly 24 are shown in which the needle assembly 24 is retracted within the barrel section 4 of the fluid passing device 2. In the embodiment shown in FIGURES 7 and 8, the needle assembly 24 is provided with a flange 90 between the base 26 and the neck 28. The flange 90 is adapted to engage under slight pressure the interior surface 92 of the collar 8 to provide axial guide means for the needle assembly 24. The base 26 is also provided with a projection 93 which is prevented from upward movement by a radially inwardly extending flange 95 on the interior surface 92 of the collar 8.

The base 26 of the needle assembly 24 is also provided with a pair of spaced-apart downwardly extending detents 96 having radially outwardly extending ledges 98 and tapered ends 100. The detents 96 extend downwardly towards the barrel 4. Extending downwardly from the bottom of the collar 8 into the barrel section 4 are a pair of spaced-apart detents 102 having radially inwardly extending ledges 104 and tapered ends 106. The ledges 104 of the detents 102 provide a stop and support for the detents 96 when the needle assembly 24 is inserted into the collar 8 and when the needle 30 is injected into the patient so that the needle assembly 24 is prevented from downward movement into the barrel 4 when used to inject or withdraw a fluid from a patient.

The head section 16 of the plunger 14 is provided with a pair of spaced-apart upwardly extending detents 108 having tapered ends 110 and radially inwardly extending ledges 112.

In operation, at the end of the injection stroke the detents 108 are moved upward in the barrel section 4 until the ends 110 press against the ends 106 of the detents 102 forcing them radially outward and further apart. As a result, the ends 100 of the detents 96 are dislodged from their supported position on the ledges 104 of the detents 102. Continued upward movement of the plunger 14 causes the ledges 112 of the detents 108 to engage the ledges 98 of the detents 96 extending from the needle assembly 24. The plunger 14 is then pulled back and thereby retracts the needle assembly 24 into the barrel section 4.

Means may also be provided for misaligning the axis of the needle 30 after retraction to prevent the needle 30 from reentering the aperture 88 of the syringe. For example, one of the detents 108 or one of the detents 96 may be made slightly longer than the other detent 96 so that the needle 30 is caused to cock to one side of the barrel 4 upon

retraction. Once the needle 30 is cocked to one side and fully withdrawn into the barrel 4, it is prevented from reentering the aperture 88 by the downwardly extending detent 102.

As shown in Figure 9, the base 26 of the needle assembly 24 may be provided with a single downwardly extending ledge 98 and a tapered end 100. The head section 16 of the plunger 14 is provided with a single upwardly extending detent 108 having a tapered end 110 and a radially inwardly extending ledge 112.

The collar 8 is provided with a downwardly extending annular lip 101 which serves to prevent the needle 30 from reentering the aperture 88 in the collar 8 after the needle 30 has been retracted.

As shown in Figure 9, the entire needle assembly 24 is withdrawn into the barrel section 4. In order to secure the needle assembly 24 within the collar 8 prior to retraction so that injection or withdrawal of fluid can be made, the base 26 is provided with a radially extending flange 103 which is releasably secured in a recess 105 of the internal surface 92 of the collar 8.

In operation, at the end of the injection stroke the plunger 14 is moved upward so that the detent 108 is likewise moved upward in the barrel section 4 until the tapered end 110 presses against the end 100 of the downwardly extending detent 96. Continued upward movement of the plunger 14 causes the ledge 112 of the detent 108 to engage the ledge 98 of the detent 96 extending from the needle assembly 24.

The plunger 14 is then pulled back thereby dislodging the flange 103 from the recess 105 enabling the needle assembly 24 to be retracted within the barrel section 4. By positioning the detents 96 and 108 off the center axis of the barrel section 4 and needle assembly 24, the tip of the needle 30 will cock to (i.e. towards the left as shown in FIGURE 9) as it passes in to the barrel section 4 and will be prevented from reentering the collar 8 by the annular lip 101 as described previously.

Another embodiment of the invention employing a square cross-sectional barrel section 4 is shown in FIGURE 10. The needle assembly 24 is secured to the barrel section 4 by a thread and groove. The needle assembly 24 includes a sheath 107 in which is secured the needle 30. The sheath 104 has thereon a flange 109 releasably secured in a recess 111. The head section 16 of the plunger 14 is provided with a pair of spaced-apart upwardly extending detents 108 having tapered ends 110 and radially inward extending ledges 112.

The sheath 107 of the needle assembly 24 is provided with a pair of spaced-apart downwardly extending detents 96 having radially outwardly extending ledges 98 and tapered ends 100.

When the upwardly extending detents 108 engage the downwardly extending detents 96, and the detents 96 are pulled downwardly, the flange 109 disengages from the recess 111 thereby allowing the sheath 107 and needle 30 to be retracted within the barrel section 4.

The aperture 88 in the barrel section 4 may be provided with a conical tapered side 114 to prevent reentry of the needle 30 after it has been retracted as previously described.

Referring to FIGURES 11 and 12, another embodiment of the retractable needle assembly type is shown. The needle assembly 24 is provided with a pair of spaced apart downwardly extending detents 120, each having a tapered end 122 and a ledge 124 and an area 126 above the ledges 124 for receiving the head of a corresponding detent attached to the top surface of the head section 16 of the plunger 14.

More specifically, the head section 16 is provided with a single upwardly extending detent 128 having a conical head 130 and a cylindrical base 132. The detent 128 is connected to the head section 16 by a stem 134. The stem 134 has a cross-sectional dimension less than that of the base 132 so that the detent 128 has a radially extending surface 136 which is adapted to engage the ledges 124 of the detents 120.

The needle assembly 24 is secured within an elongated needle assembly sleeve 140 having a securing means 32 including an arcuate surface 31 adapted to reversibly screw into the collar 8 as previously described. The needle assembly 24 is provided with a tapered head section 150 which is adapted to reversibly friction lock the needle assembly 24 within the sleeve 140, or otherwise releasably secure the needle assembly 24 within the sleeve 140.

As shown best in FIGURE 12, as the plunger 14 is moved toward the peak of the injection stroke, the detent 128 extending upwardly from the head 16 of the plunger 14 engages the tapered sides 122 of the detents 120 and forces them apart. At about the peak of the injection stroke the surface 136 of the detent 128 rests upon the ledges 124 of the detents 120. As the motion of the plunger 14 is reversed (i.e., retracted within the barrel), the detent 128 pulls the detents 120 downwardly thereby releasing the needle assembly 24 from the sleeve 140 and retracting the needle assembly 24 within the barrel section 4.

The aperture of the barrel 4 may be provided with conical tapered sides (not shown) to prevent the needle from reentering the aperture as described previously in connection with the embodiments of FIGURES 9 and 10.

The relative position of the detents 120 may be angled with respect to the longitudinal axis of the

needle assembly 24 to create an effective means of cocking the needle 30 as it is retracted into the barrel 4.

Referring to FIGURE 13, each of the detents 120 is provided with an inner side 162 which is angled with respect to longitudinal axis of the needle assembly 24 by an angle  $\theta$  which for practical purposes can be up to  $45^\circ$ , preferably in the range of about  $10$  to  $25^\circ$ . As a result, the space 164 between the respective detents 120 is essentially rectangular but may be constructed in any shape so long as the space 164 is sufficient to permit entry and engagement by the detent 128.

The outside surface 166 of one of the detents 120 (the right detent as shown in FIGURE 13) tapers inwardly by an angle  $\alpha$  which can be the same or different than the angle  $\theta$  described above. It is preferred for ease of construction that inner side 162 and outer side 166 are parallel (i.e. angle  $\theta = \text{angle } \alpha$ ). The detents 120 are preferably made of a flexible plastic having a memory.

In operation, the detent 128 attached to the head 16 of the plunger 14 is moved into engagement with the detents 120. During this process the conical head 130 of the detent 128 engages and forces apart the tapered sides 122 of the detents 120 thereby forcing the outer side surface 166 of the right hand detent 120 to move from the angled position shown in FIGURE 13 to a position where the outside surfaces 166 of each of the detents 120 are parallel to each other and to the longitudinal axis of the needle assembly 24 (i.e. angle  $\alpha = 0^\circ$ ).

This procedure creates radial tension in the right hand detent 120 which seeks to return to its original angled position. As the plunger 14 is retracted thereby pulling the needle assembly 24 downward into the barrel 4, the radial tension in the right hand detent 120 is transmitted to the needle assembly 24 causing the needle 30 to cock to the left. The cocked needle 30 is also prevented from reentering the aperture by conical tapered sides 101 as previously described in connection with FIGURE 9 and 114 of FIGURE 10 for example.

Referring to FIGURE 14 there is shown a modification of the embodiment described in connection with FIGURE 9 in which the plunger itself cooperates to provide radial tension against the single downwardly extending detent which serves to facilitate cocking of the needle as it is retracted into the barrel.

More specifically, the plunger 14 is provided with an inner wall 170 which is tapered by an angle  $\beta$  with respect to the longitudinal axis of the needle 30 and thereby creates radial tension against the side wall 172 of the downwardly extending detent 96 in a direction substantially perpendicular to the axis of the needle 30. In addition, a gap 174 is created between the respective upper portions of

the detent 96 and the wall 170.

The angle of taper may be the same as that described previous for the angles  $\theta$  and  $\alpha$  (i.e. up to  $45^\circ$ , preferably from about  $10$  to  $25^\circ$ ). The detent 96 and the plunger wall 170 may preferably be made of a flexible plastic having a memory to facilitate the radial tension and eventual cocking of the needle 30 in the barrel 4.

The operation of the embodiment shown in FIGURE 14 is similar to that described with respect to FIGURE 9. Radial tension exists at the junction of the detent wall 172 and the plunger wall 170. As the needle 30 is drawn into the barrel 4 the detent 96 seeks to relieve the radial tension by moving to the right and thereby occupy the space of the gap 174 and is thereby cocked toward the right as the needle is fully retracted. The needle 30 is prevented from reentering the aperture 88 by the conical tapered sides 101 described previously.

The features shown in the embodiments described herein may be modified by those skilled in the art within the spirit and scope of the invention. For example, the needle assembly may be provided with more than two detents so long as the detents extending upwardly from the plunger are able to engage and draw the needle assembly downward within the barrel.

As previously indicated in connection with FIGURES 7, 8 and 10, the barrel 4 may have a rectilinear cross section so that the detents 108 extending upwardly from the plunger 14 are always precisely aligned with the downwardly extending detents 96. In this way, the user does not have to visually observe the movement of the plunger 14.

The present invention provides a novel and commercially viable means for covering a contaminated needle or other fluid passing device in which exposure to the contaminated needle is virtually eliminated and reentry of the needle in the aperture prevented. Additionally, the present invention retains the commercially required top loading exteriorly mounted needle assembly which allows for easy loading and interchangeability of needles.

## Claims

1. Apparatus for passing a fluid from one location to another comprising:

- (a) a body adapted to contain the fluid;
- (b) fluid passing means in flow communication with the body;
- (c) means for mounting the fluid passing means on the exterior surface of the body; and
- (d) means connected to the mounting means for covering the fluid passing means after the passing of the the fluid has terminated.

2. Apparatus for passing a fluid into or out of a warm-blooded animal or tissue thereof comprising:

- (a) a body adapted to contain said fluid;
- (b) fluid passing means in flow communication with said body and adapted to penetrate the warm-blooded animal or tissue thereof;
- (c) means for mounting the fluid passing means on the exterior surface of the body;
- (d) means for urging said fluid out of or into said body through said fluid passing means; and
- (e) means connected to said mounting means for covering said fluid passing means after the fluid has been passed into or out of the body of the apparatus.

3. The apparatus of Claim 2, wherein the fluid passing means comprises:

- (a) a base having a pair of opposed ends;
- (b) needle means affixed to one end of the base; and
- (c) means for releasably securing the other end of the base to the body.

4. The apparatus of Claim 3, wherein the cover means comprises a cap comprising a body having a top end including an opening for receiving the needle means, a bottom end adapted to be secured to the base of the fluid passing means, and means for moving the body of the cap from a compressed position wherein the needle means extends through the opening in the top end of the cap and is in the operable position for passing fluid into or out of said warm-blooded animal, to an extended position wherein the cap moves upwardly and above the needle means thereby encasing the needle means within the cap.

5. The apparatus of Claim 4 further comprising means for releasably retaining said cap in the compressed position.

6. The apparatus of Claim 4 further comprising means for offsetting the axis of the cap from the axis of the needle means when the cap is moved to the extended position encasing the needle means, whereby the needle means is prevented from re-entering the opening in the top end of the cap.

7. The apparatus of Claim 4, wherein the cap further comprises at least one pair of arms hingedly attached to the cap body and to each other, said arms extending essentially perpendicular from the axis of the needle means when the cap is in the compressed position and being movable to a position wherein the arms extend essentially parallel to the axis of the needle means when the cap is in the extended position encasing the needle means.

8. The apparatus of Claim 7 wherein the cap comprises one pair of said arms.



9. The apparatus of Claim 7, wherein the cap comprises two pairs of arms attached to opposed sides of the cap body.

10. The apparatus of Claim 7 further comprising means for offsetting the axis of the cap from the axis of the needle means when the cap is moved to the extended position encasing the needle means, whereby the needle means is prevented from reentering the opening in the top end of the cap.

11. The apparatus of Claim 10, wherein the offsetting means comprises one pair of said at least one pair of arms having a length in the extended position which exceeds the length in the extended position of the other pair of arms, wherein when the cap body is moved to the extended position, the cap is moved radially over the needle means in a direction away from the longest pair of extended arms.

12. The apparatus of Claim 11, wherein the cap comprises two pairs of arms attached to opposed sides of the cap body.

13. The apparatus of Claim 5, wherein the cap retaining means comprises an annular flange about the base of the fluid passing means and an annular groove in the interior surface of the cap, said flange being releasably insertable into said groove when said cap is in the compressed position.

14. The apparatus of Claim 10, wherein the offsetting means further comprises a conical tapered side integral with the bottom of the opening in the top end of the cap.

15. The apparatus of Claim 7 wherein each of said at least one pair of arms is movable to a position extending substantially parallel to the axis of the needle means about the hinges connecting the pair of arms to the cap body to facilitate packaging of the apparatus.

16. The apparatus of Claim 4, wherein the fluid passing means further comprises an axially extending annular cavity and means for securing the bottom end of the cap within the cavity.

17. The apparatus of Claim 16, wherein the securing means is an adhesive.

18. The apparatus of Claim 16, wherein the cap body is made of a compressible material, said cap being movable from the compressed position within the axially extending annular cavity exposing the needle means to the extended position wherein a portion of the cap moves out of the cavity upwardly and above the needle means thereby encasing the needle means within the cap.

19. The apparatus of Claim 16 further comprising means for releasably retaining the cap in the compressed position.

20. The apparatus of Claim 19, wherein the cap retaining means comprises a radially extending projection at the top end of the cap and a projec-

tion receiving slot in the base of the fluid passing means, said projection being releasably retained in the slot when the cap is in the compressed position and movable out of the slot when the cap is moved to the extended position encasing the needle means.

21. The apparatus of Claim 16 further comprising means for offsetting the axis of the cap from the axis of the needle means when the cap is moved to the extended position encasing the needle means, whereby the needle means is prevented from reentering the opening in the top end of the cap.

22. The apparatus of Claim 21 wherein the offsetting means comprises, said bottom end of the cap having a radially extending flange, a portion of the flange having a greater thickness than the remaining portion of the flange.

23. The apparatus of Claim 22 wherein the offsetting means further comprises a conical tapered side integral with the bottom of the opening in the top end of the cap.

24. The apparatus of the Claim 3, wherein the fluid urging means comprises a plunger movable axially within the body of the apparatus and comprising a head section having at least one outer surface in communication with the interior surface of the body and a stem connected at one end to the head section.

25. The apparatus of Claim 24 further comprising means for retracting the fluid passing means within the body of the apparatus.

26. The apparatus of Claim 25, wherein the retracting means comprises:

(a) at least one axially extending first engageable member connected to the end of the base of the fluid passing means which is remote from the needle means, said first engageable member adapted to be within the body of the apparatus when the fluid passing means is secured to the body; and

(b) at least one axially extending second engageable member connected to the head section of the plunger, said first and second engageable members adapted to engage each other on an upward stroke of the plunger and the fluid passing means being retracted into the body of the apparatus on a downward stroke of the plunger.

27. The apparatus of Claim 26 further comprising means within the body of the apparatus for supporting the first engageable member.

28. The apparatus of Claim 27, wherein the first engageable member comprises two spaced apart detents extending from the fluid passing means in the opposite direction of the needle means, each detent having a tapered end and a radially extending ledge, the second engageable member com-

prising at least one detent having a tapered end and a radially extending ledge that is adapted to be mounted upon the ledge of the first member when the first and second members engage each other.

29. The apparatus of Claim 28, wherein the second engageable member has two spaced apart detents.

30. The apparatus of Claim 29, wherein the second engageable member has a single detent.

31. The apparatus of Claim 27, wherein the support means comprises two spaced apart detents connected to the top end of the body of the apparatus and extending axially within the body, each detent comprising a tapered end and a radially inwardly extending ledge, the tapered ends of the first member being in contact and supported by the ledges of the detents of the support means when the fluid passing means is mounted to the body of the apparatus.

32. The apparatus of Claim 31, wherein the detents of the second engageable member are adapted to contact and spread apart the detents of the support means thereby releasing the first engageable member for engagement by the second engageable member.

33. The apparatus of Claim 26 further comprising means for offsetting the axis of the fluid passing means as it is retracted into the body of the apparatus thereby preventing the fluid passing means from reentering the body of the apparatus.

34. The apparatus of Claim 33 wherein the offsetting means comprises one of said first or second engageable members having a different length than the other of said first or second engageable member wherein which the fluid passing means is retracted into the body, the needle is cocked to one side of the body.

35. The apparatus of Claim 26 comprising a single first and second engageable member offset from the axis of the body of the apparatus.

36. The apparatus of Claim 26 wherein the offsetting means comprises a conical tapered side integral with the opening in the body.

37. The apparatus of Claim 26 wherein the body has a rectilinear shape having four sides and the head section of the plunger having four sides adapted to sealingly engage the sides of the body wherein the radial position of the plunger is fixed during axial movement of the plunger within the body, to thereby enable the first engageable member to be precisely aligned with the second engageable member when the members are engaged to each other on the upward stroke of the plunger.

38. The apparatus of Claim 28 wherein the spaced apart detents have opposed inner sides, said sides being angled with respect to the longitu-

dinal axis of the needle means, the outer surface of one of the detents being angled with respect to the longitudinal axis of the needle assembly.

39. The apparatus of Claim 38 wherein the first engageable member has a single detent adapted to engage and spread apart the spaced apart detents of the first engageable member thereby causing radial tension in said angled detent, wherein when the needle means is retracted into the body, the needle means cocks to one side of the body and is thereby prevented from exiting the body.

40. The apparatus of Claim 28 wherein the first and second engageable members each comprise a single detent, said plunger having a inner wall adapted to exert radially directed pressure contact on the detent of the first engageable member and to release said pressure when the fluid passing means is retracted into the body of the apparatus.

41. The apparatus of Claim 40 wherein the inner wall of the plunger is angled with respect to the axis of the fluid passing means in the direction of the detent of the first engageable member.

42. The apparatus of Claim 41 wherein the inner wall of the plunger and the detent of the first angled member each comprise corresponding upper and lower portions, whereby the lower portion of the inner wall of the plunger is adapted to contact the lower portion of said detent, said respective upper portions having a gap therebetween, wherein when the fluid passing means is retracted into the body of the apparatus the radial tension exerted on the lower portion of the detent causes the upper portion of the detent to move toward the upper portion of the inner wall of the plunger thereby causing the needle to cock to one side of the body.

43. The apparatus of Claim 42 wherein the offsetting means comprises a conical tapered side integral with the opening of the body.

44. The apparatus of Claim 42 wherein the body has a rectilinear shape having four sides and the head section of the plunger has four sides adapted to sealingly engage the sides of the body wherein the radial position of the plunger is fixed during axial movement of the plunger within the body, to thereby enable the first engageable member to be precisely aligned with the second engageable member when the members are engaged to each other.

FIG. 1

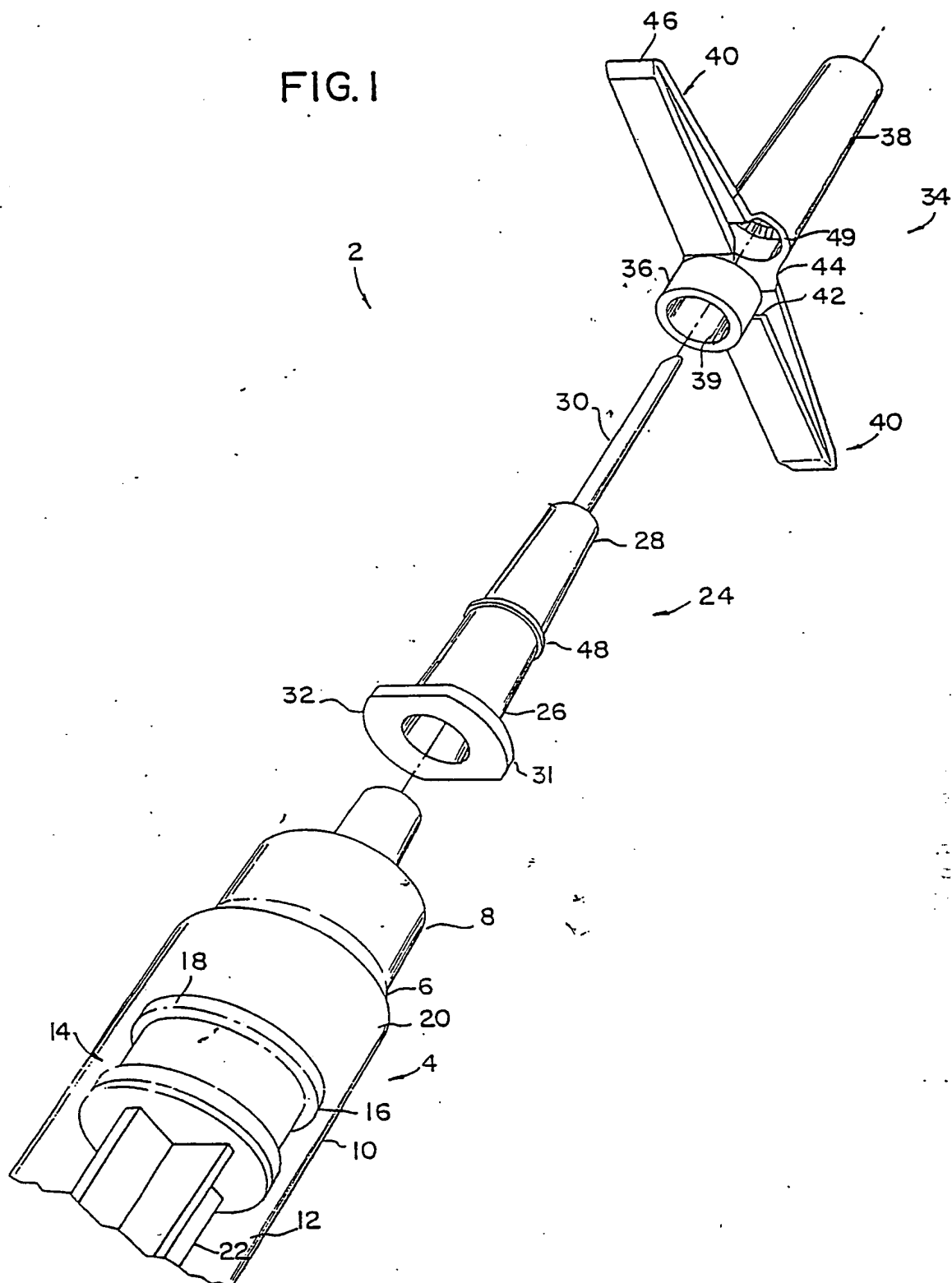
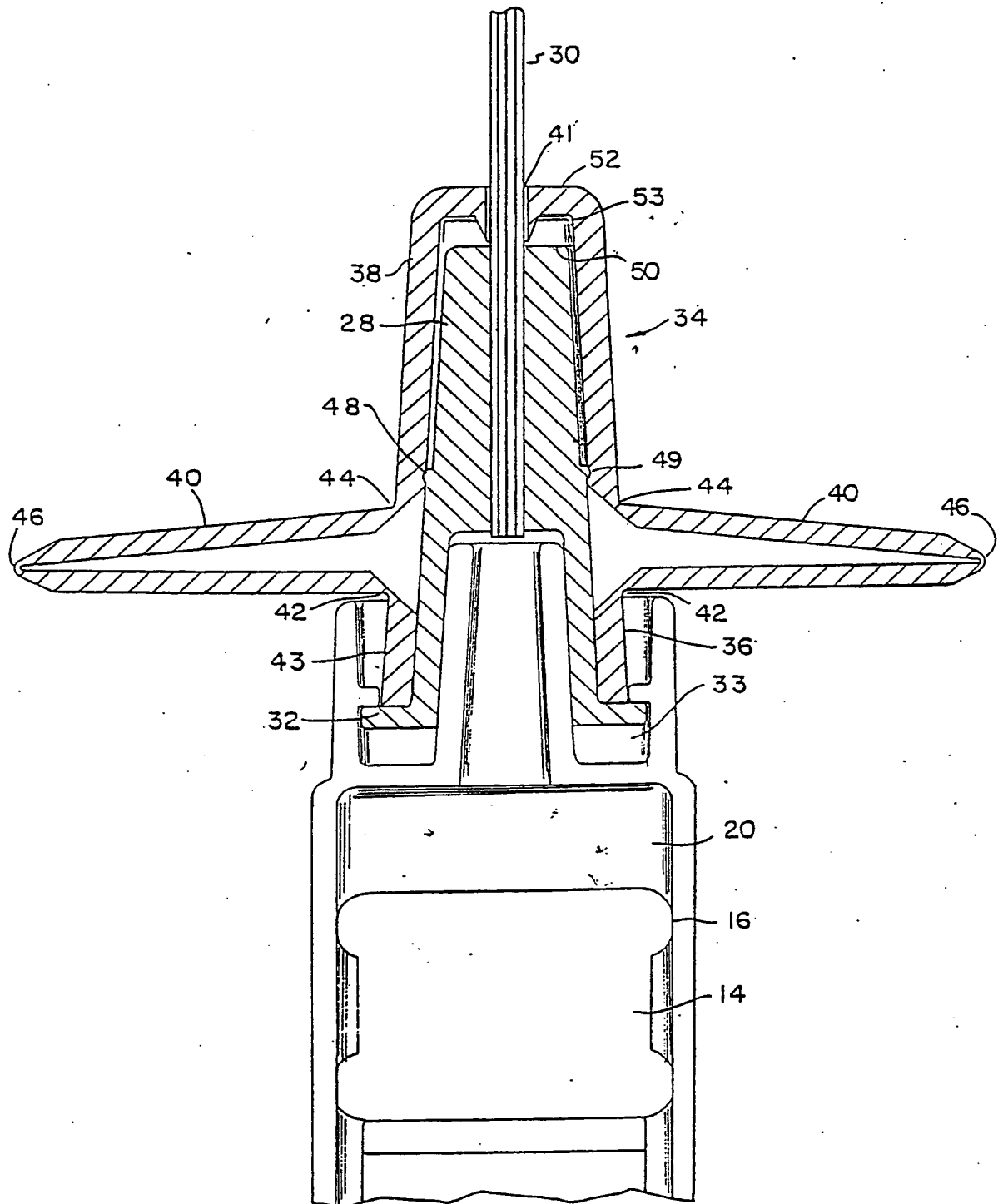


FIG. 2



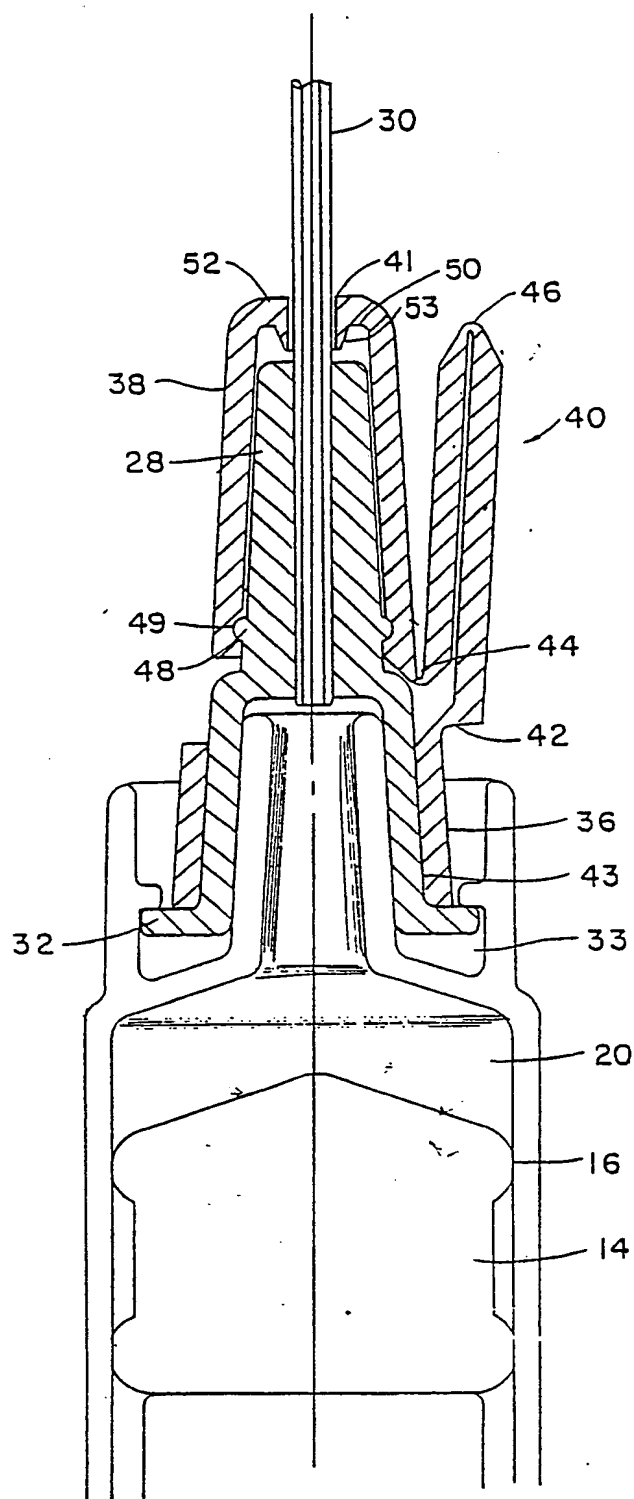


FIG. 3

FIG. 4

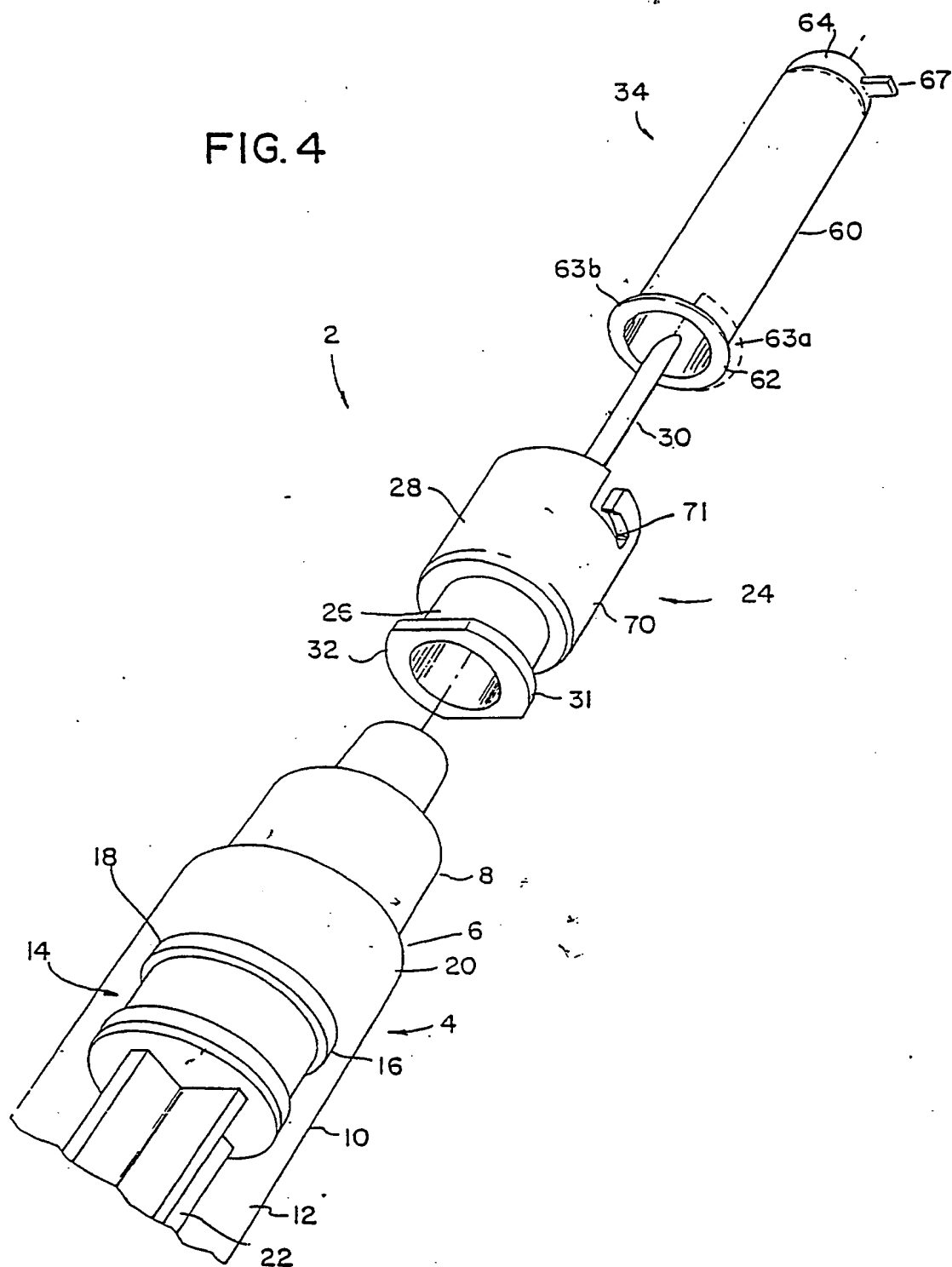


FIG. 5

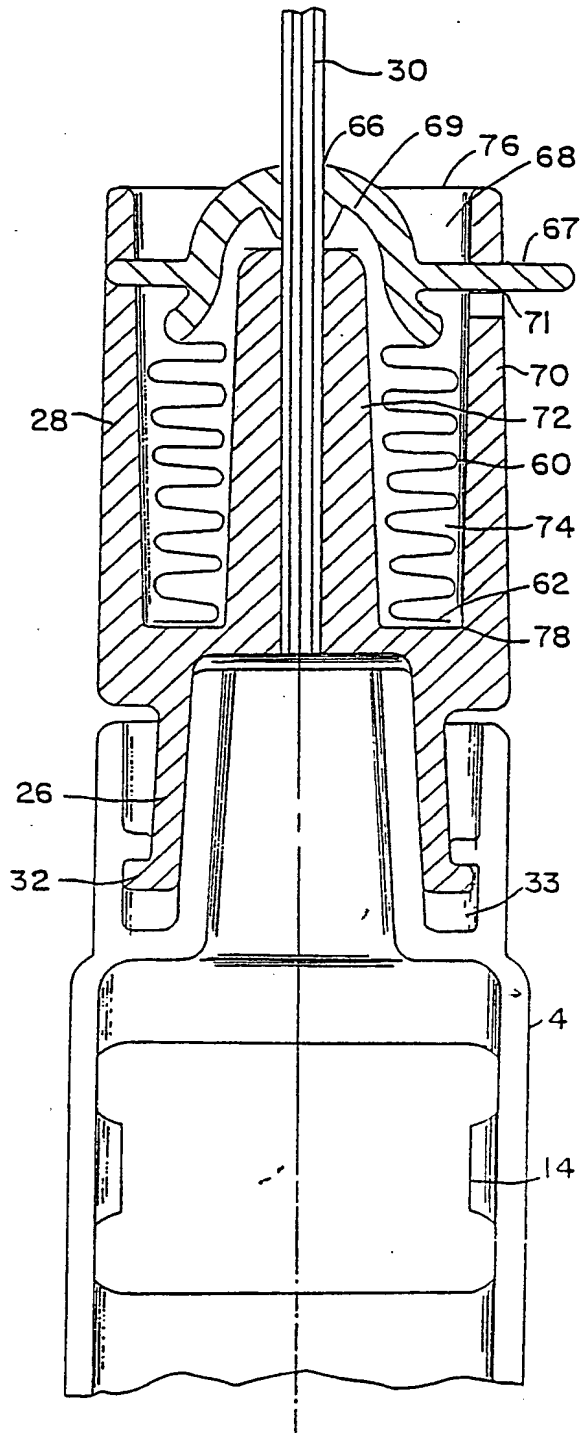
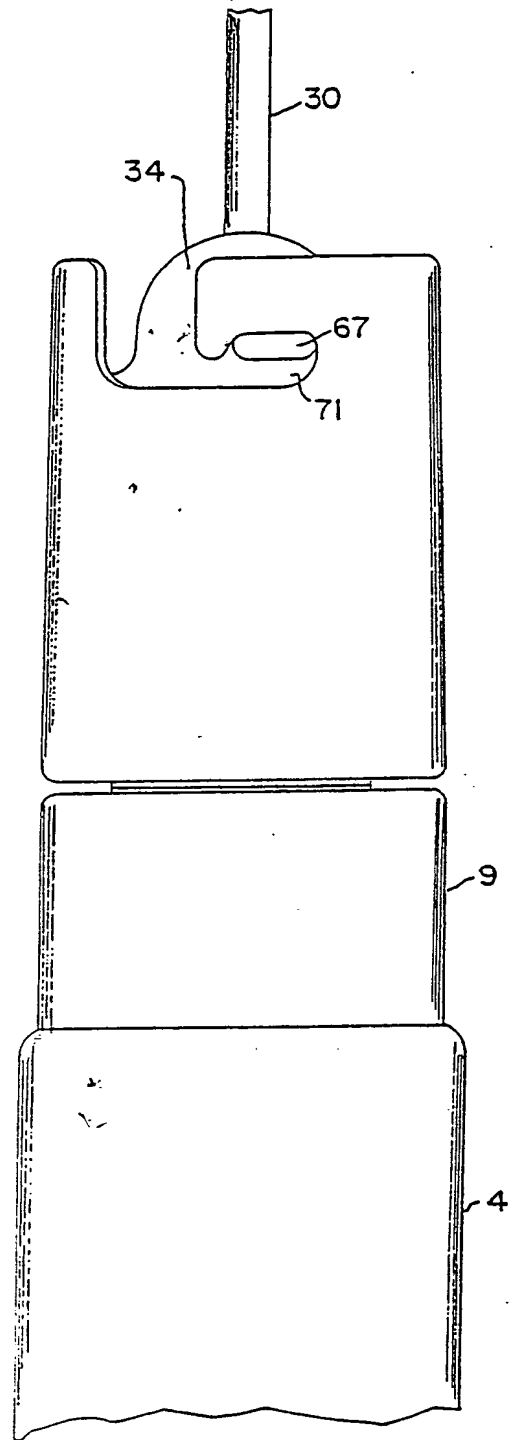


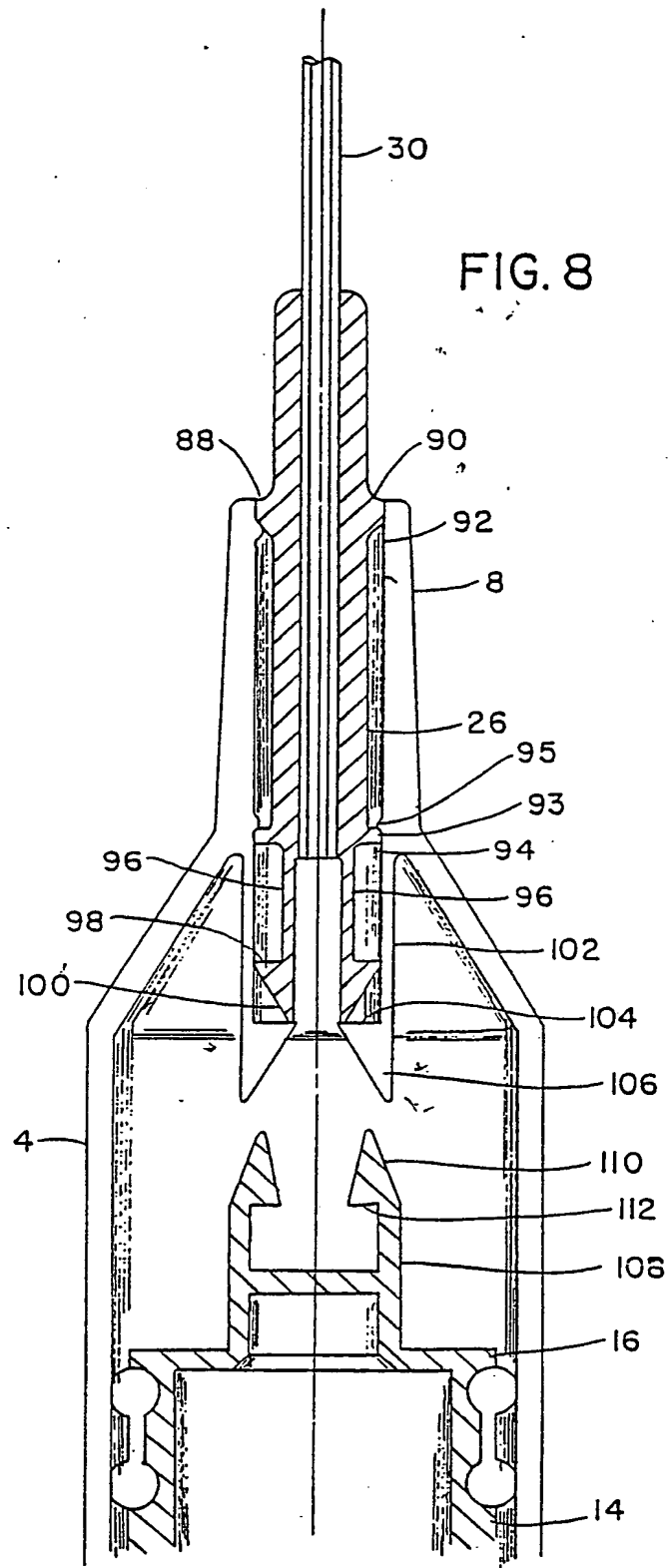
FIG. 6



2







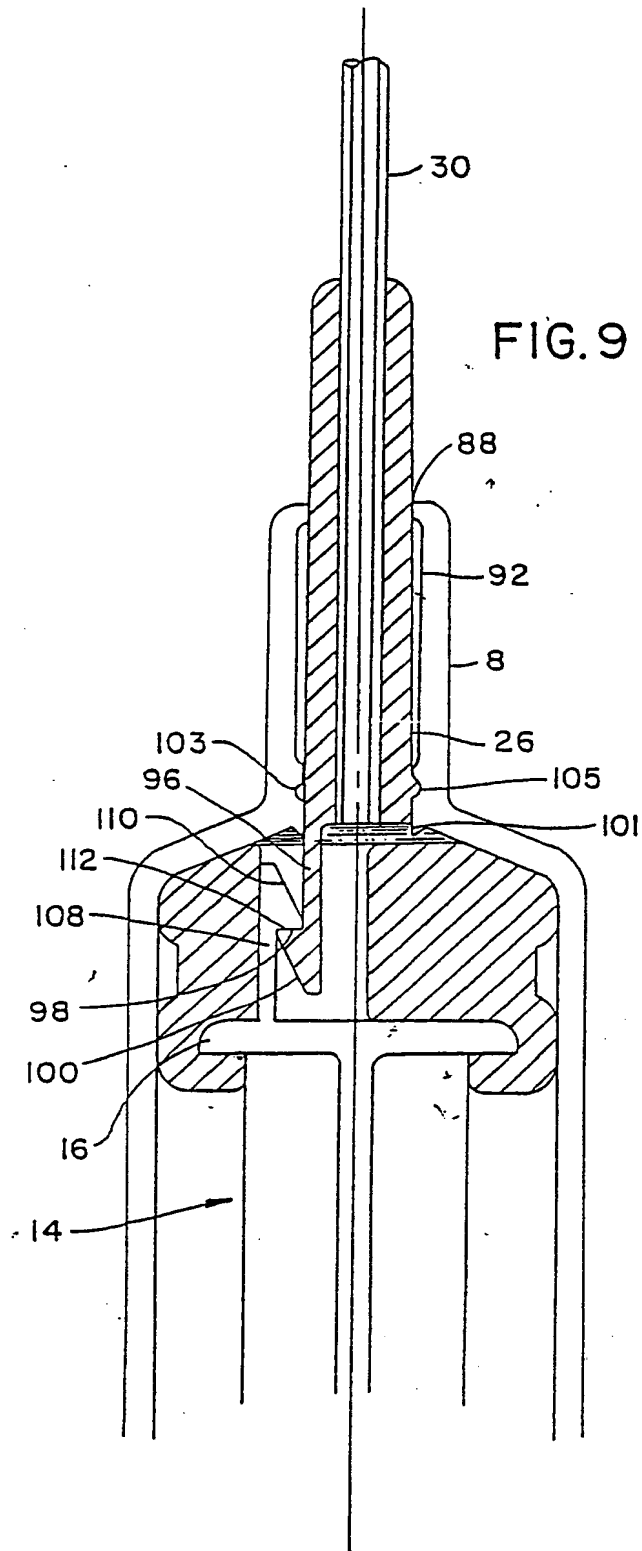


FIG.10

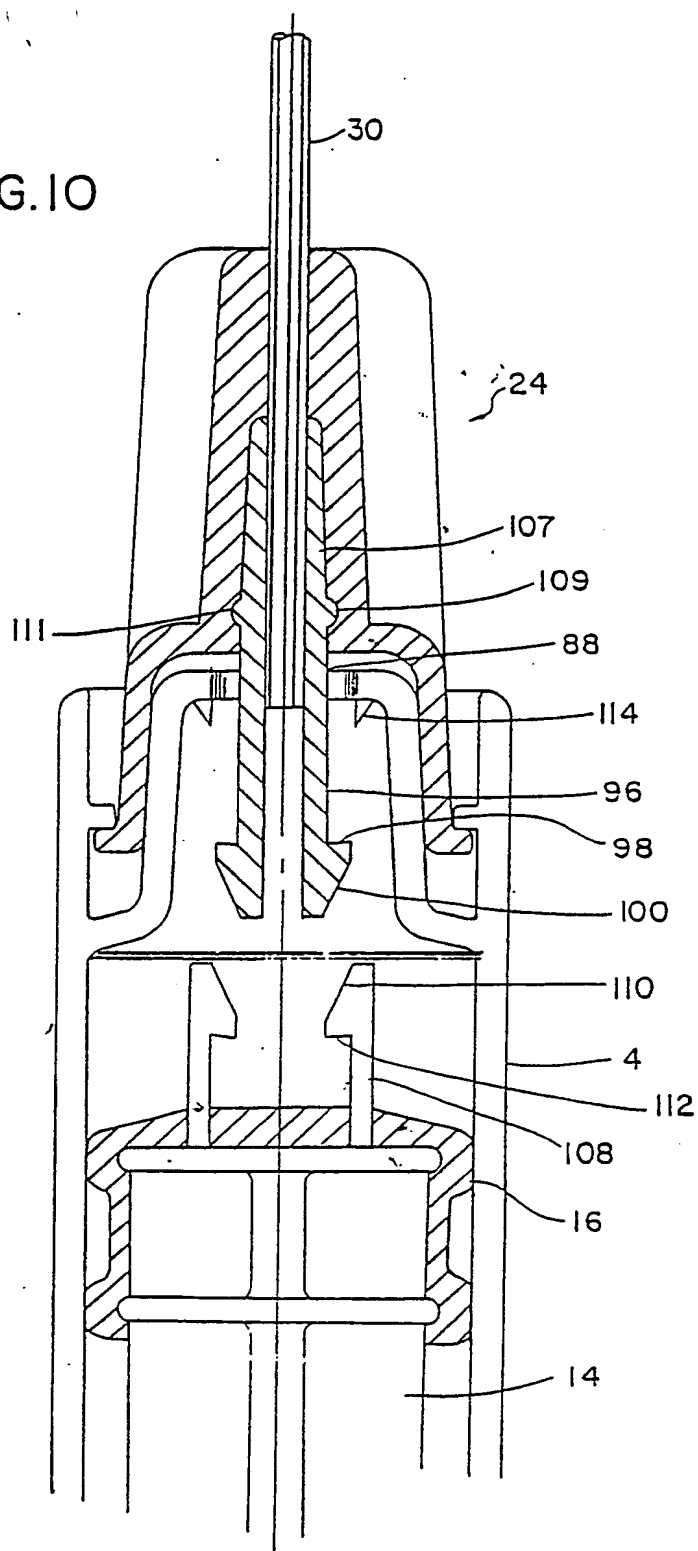


FIG. 11

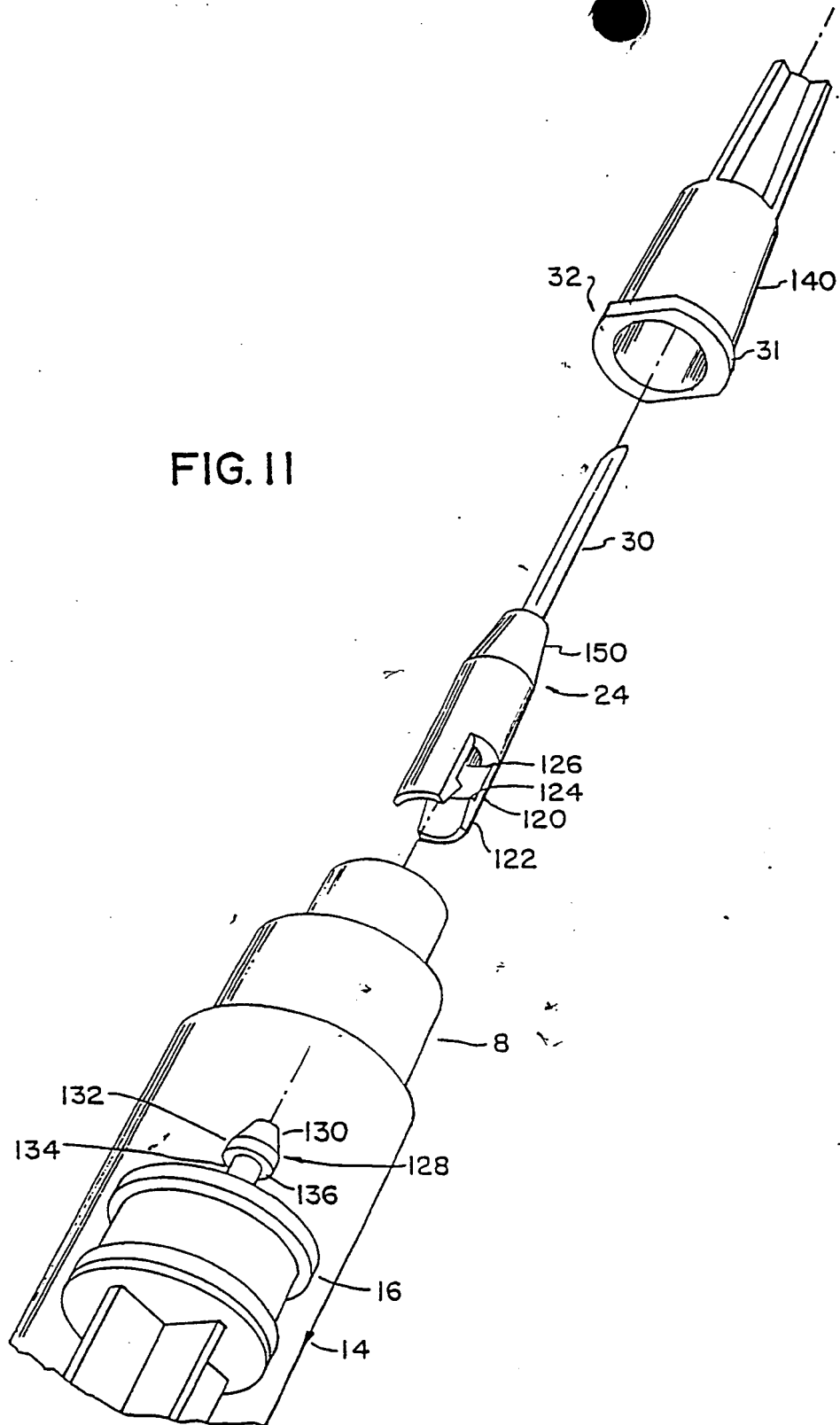
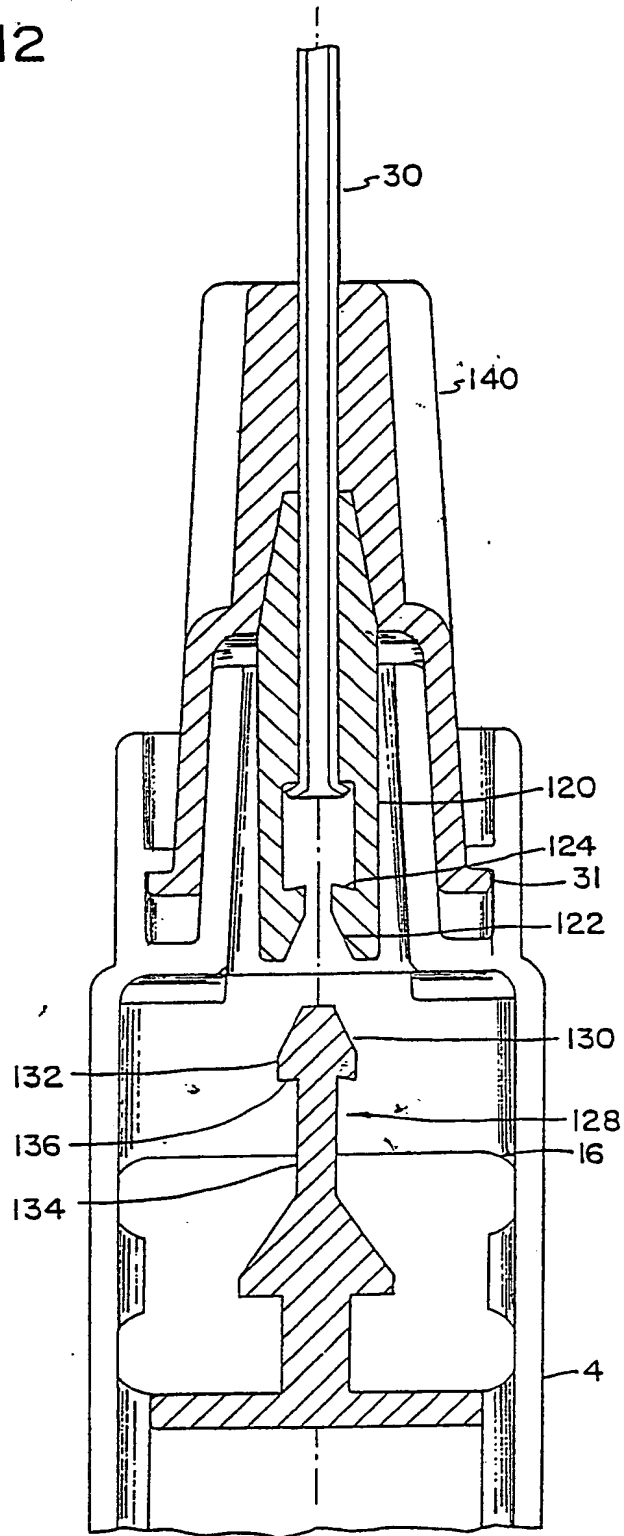


FIG.12



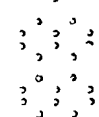
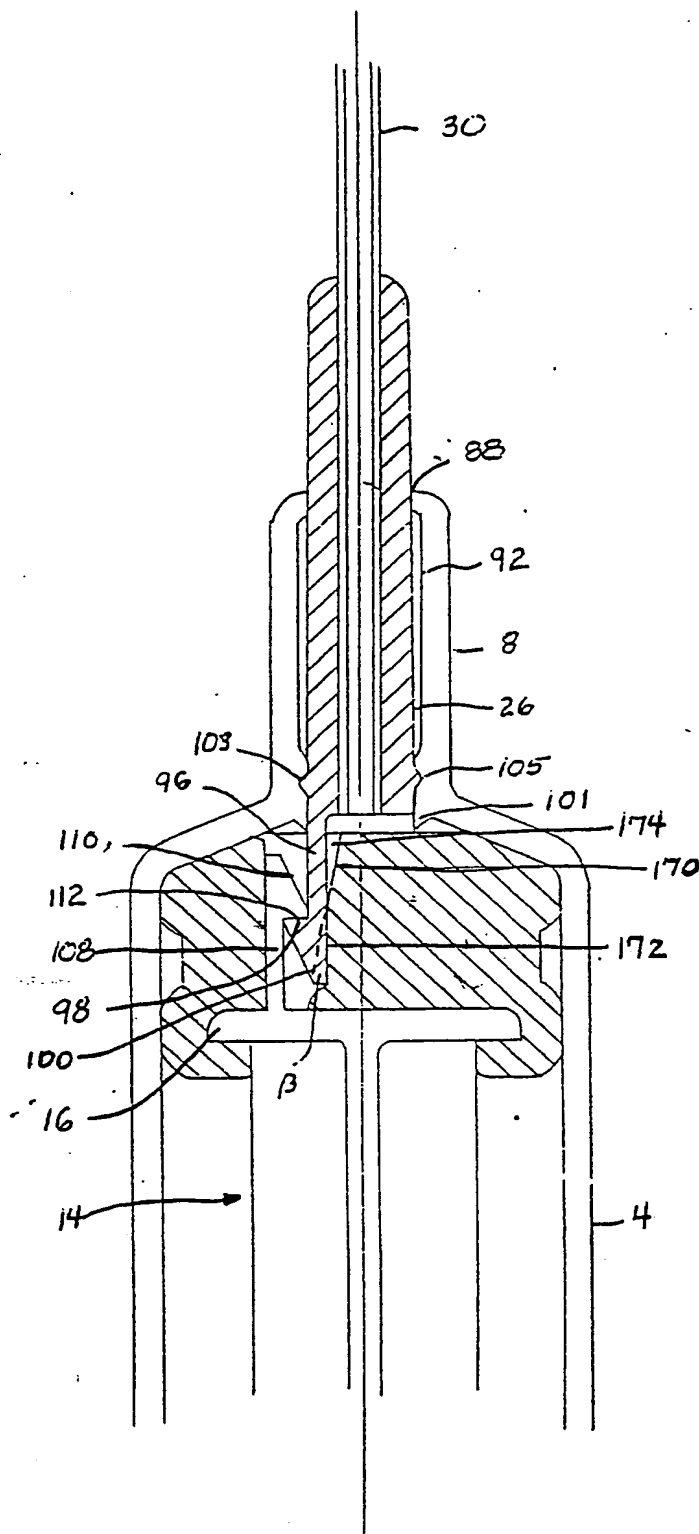
[illegible]

FIG. 14



**THIS PAGE BLANK (USPTO)**



12

# EUROPEAN PATENT APPLICATION

21 Application number: 88121221.1

51 Int. Cl. 4: A61M 5/00

22 Date of filing: 19.12.88

30 Priority: 21.12.87 US 135581  
 09.03.88 US 166046  
 07.09.88 US 241352

43 Date of publication of application:  
 28.06.89 Bulletin 89/26

84 Designated Contracting States:  
 AT BE CH DE ES FR GB GR IT LI LU NL SE

88 Date of deferred publication of the search report:  
 15.11.89 Bulletin 89/46

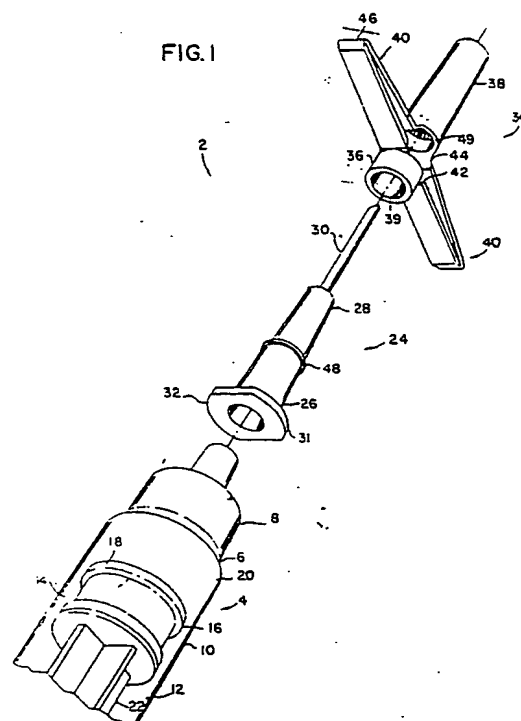
71 Applicant: Dolgin, Stuart M.  
 95 Belvedere Drive  
 Syosset, NY 11791(US)

72 Inventor: Dolgin, Stuart M.  
 95 Belvedere Drive  
 Syosset, NY 11791(US)  
 Inventor: Torbet, Philip  
 26 Centre View Drive  
 Upper Brookville, NY 11771(US)

74 Representative: Perani, Aurelio et al  
 c/o JACOBACCI-CASETTA & PERANI 7, Via  
 Visconti di Modrone  
 I-20122 Milano(IT)

54 Fluid passing apparatus with means for covering the same.

57 Apparatus for passing a fluid into or out of a warm-blooded animal which includes a fluid containing body (4), a needle assembly (24) releasably mountable on the exterior surface of the body, a plunger (14) for urging fluid into or out of the body and an externally mounted cap (34) or retraction device for automatically covering the needle after it has been used and preventing the needle from reentering the aperture in the body.



EP 0 321 903 A3



EP 88 12 1221

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl. 4)
X,P	US-A-4 735 618 (HAGEN) * Figures 1-4; column 5, line 23 - column 7, line 6 *	1-4, 6- 12, 14, 15, 23	A 61 M 5/32
Y,P		5, 13, 16 , 17, 20, 24, 25, 26, 29, 33, 34, 36	
Y	--- US-A-3 134 380 (ARMAO) * Figures 6, 7 *	16, 17	
A,D	--- US-A-4 695 274 (FOX) * Figures 3, 4, 5 *	19	
Y	--- US-A-4 693 708 (WANDERER et al.) * Figures 1-4, 13, 14; column 4, line 64 - column 5, line 6; column 5, lines 9, 14-16; column 6, lines 59-65 *	5, 13, 20	
Y,P	--- US-A-4 747 830 (GLOYER et al.) * Figures 5, 5a, 8, 12, 13; column 4, lines 51-60 *	24, 25	TECHNICAL FIELDS SEARCHED (Int. Cl. 4)
Y,P	--- EP-A-0 282 097 (HABLEY MEDICAL TECHNOLOGY) * Figures 1-5 *	26, 29, 33, 34, 36	A 61 M
A,P	--- US-A-4 139 009 (ALVAREZ) * Figures 1-5 *	28, 30	
A	----- US-A-4 139 009 (ALVAREZ) * Figures 1-5 *	1	
The present search report has been drawn up for all claims			
Place of search THE HAGUE		Date of completion of the search 06-09-1989	Examiner SEDY, R.
CATEGORY OF CITED DOCUMENTS X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document		T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons ----- & : member of the same patent family, corresponding document	

EPO FORM 1503 03.82 (P0401)